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Signature: *[Signature]*

(Jeffrey S. Sharp)

Dated: NOV 06 2002Docket No.: 28911/36128/US  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Alison Hopkins

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NOV 08 2002

Application No.: 09/485,245

Group Art Unit: 1655

TECH CENTER 1600/2900

Filed: March 27, 2000

Examiner: C. Wilder

For: LABELLING COMPOSITION AND METHODDECLARATION OF ALISON HOPKINS UNDER 37 CFR 1.132

Box AF

Commissioner for Patents  
Washington, DC 20231

1. I, Alison Hopkins, declare that I am the inventor of the subject matter described and claimed in the above-identified patent application and that I am experienced in the arts of molecular biology and including the art of random prime labeling of nucleic acids.

2. I submit this declaration to address issues raised in the Office Action dated May 1, 2002 in the above-identified application as well as in the Interview with the Examiner conducted May 14, 2002.

3. In response to the questions presented about the identity and criticality of the buffer used in the experiments presented in the specification, I declare that the buffer recited in claim 2 is not critical to the demonstration of the unexpected results presented on pages 8 and 9 of the application. The specification at page 7, lines 2 and 3 describes a commercially available nucleotide buffer (N5000/N5500 Amersham International plc, see the Exhibit attached hereto) which comprises Tris-HCl, pH 7.8, MgCl<sub>2</sub> and 2-mercaptoethanol. The specification further teaches that other buffers could be used depending upon the particular polymerase enzymes at page 4, lines 13 through 17 of the specification. The selection of this suitable buffer would be within the scope of a knowledgeable person and would not influence implementation of the invention.

Application No.: 09/485245

4. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Alison Hopkins

Alison Hopkins

October <sup>22<sup>nd</sup></sup>, 2002



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N 5000/N 5500 pages 11/1/02 2:17 PM Page 1

## Nick translation kit

N 5000 For radioactive probe preparation  
N 5500 For radioactive and non-radioactive probe preparation

### STORAGE

Store at -15°C to -30°C  
in a non frost-free freezer.

### STABILITY

Stable for 3 months,  
stored as recommended

Warning: For research use only.  
Not recommended or intended for diagnosis  
of disease in humans or animals. Do not use  
internally or externally in humans or animals.

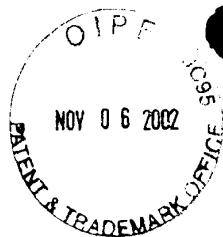


amersham pharmacia biotech

## COMPONENTS OF THE SYSTEM

Nick translation systems		N 5000	N 5500
Nucleotide/buffer solution; 100mM each of dATP, dGTP and dTTP in Tris HCl pH7.8, 2 mercaptoethanol, and MgCl <sub>2</sub>		400µl	-
Nucleotide solutions; in Tris-HCl pH7.8, 2-mercaptoethanol and MgCl <sub>2</sub>			
300µM dATP	-		150µl
300µM dGTP	-		150µl
300µM dTTP	-		150µl
Enzyme solution; 0.5 units/µl DNA polymerase I and 10µg/µl DNase I in Tris-HCl pH7.5, MgCl <sub>2</sub> , glycerol and bovine serum albumin		200µl	200µl
Standard DNA solution; 200ng/µl Hind III digested lambda DNA in 10mM Tris-HCl pH8.0, 1mM EDTA		25µl	25µl
Water		2x1ml	2x1ml

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